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Attorneys for Defendants
XIROMED PHARMA ESPANA, S.L.
XIROMED, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	Civil Action No. 2:24-cv-07791-BRM-CLW (Consolidated)

DEFENDANT'S ANSWER, DEFENSES, AND
COUNTERCLAIM TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants Xiromed, LLC and Xiromed Pharma España, S.L. (collectively, "Xiromed " or "Defendants") for their Answer, Defenses, and Counterclaims against Plaintiff American Regent, Inc., by its undersigned attorneys, alleges as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Xiromed's submission to the United States Food and Drug

Administration ("FDA") of Abbreviated New Drug Application No. 219476 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation a generic version of ARI's Selenious Acid products ("the ANDA Product") prior to the expiration of United States Patent No. 12,150,957 ("the '957 patent" or the "Asserted Patent"). As discussed below, this case involves the same ANDA No. 219476 and thus is a related case to *American Regent, Inc. v. Xiromed, LLC, et al.*, C.A. No. 24-7811 (D.N.J.) (the "Related Action").

ANSWER: Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, denied, except to admit the Complaint purports to set forth claims of patent infringement concerning the '957 Patent. Xiromed further admits that Xiromed filed its ANDA No. 219476 ("the ANDA") to obtain approval from FDA to engage in the commercial manufacture, use, and/or sale of a single dosage strength of ARI's Selenious Acid product ("the ANDA Product"). Xiromed further admits the ANDA contains a Paragraph IV certification, and this is a Related Action.

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Xiromed is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and therefore, Xiromed denies the allegations in Paragraph 2.

3. On information and belief, Xiromed Pharma España, S.L. is a corporation organized and existing under the laws of Spain with its principal place of business at Manuel Pombo Angulo, 28 3rd Floor, Madrid, Spain, 28050.

ANSWER: Admitted.

4. On information and belief, Xiromed, LLC is an American corporation organized and existing under the laws of New Jersey with its principal place of business at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

ANSWER: Admitted.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 5 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Count 1 of the Complaint arises under the patent laws of the United States, and that this Court has subject matter jurisdiction for Count 1 under 35 U.S.C. § 271(e) only.

6. On information and belief, this Court has personal jurisdiction over Xiromed, LLC, under the New Jersey state long arm statute and consistent with due process of law because Xiromed, LLC has extensive contacts with the State of New Jersey, has its principal place of business in New Jersey, and regularly does business in this judicial district. Further, Xiromed, LLC plans to sell the ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: Paragraph 6 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed, LLC does not contest personal jurisdiction in this Court for purposes of this action only.

7. On information and belief, this Court has personal jurisdiction over Xiromed Pharma España, S.L., under the New Jersey state long arm statute and consistent with due process of law because Xiromed Pharma España, S.L. has extensive contacts with the State of New Jersey, including through its affiliate Xiromed, LLC, and regularly does business in this judicial district. Further, Xiromed Pharma España, S.L. plans to sell the ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for purposes of this action only.

8. This Court has personal jurisdiction over Xiromed, LLC by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Xiromed, LLC Inc.'s principal place of business is in Warren, New Jersey. On information and belief, Xiromed, LLC Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0600430486. On information and belief, Xiromed, LLC purposefully has conducted and continues to conduct business in this judicial district. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Xiromed, LLC.

ANSWER: Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed, LLC has a place of business and is registered to do business in New Jersey under Business Id. No. 0600430486.

Xiromed, LLC further admits it does not contest personal jurisdiction in this Court for purposes of this action only.

9. This Court has personal jurisdiction over Xiromed, LLC because Xiromed, LLC derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed, LLC does not contest personal jurisdiction in this Court for purposes of this action only.

10. On information and belief, Xiromed, LLC is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Denied, except to admit that Xiromed, LLC is a corporation located in Florham Park, New Jersey and that certain corporate Xiromed entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products.

11. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Xiromed, LLC, and (2) has maintained extensive and systematic contacts with the State of New Jersey, including, directly or indirectly, preparation and submission of the ANDA to the FDA in New Jersey through Xiromed, LLC.

ANSWER: Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for purposes of this action only.

12. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because Xiromed Pharma España, S.L. derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for purposes of this action only.

13. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because, *inter alia*, Xiromed Pharma España, S.L. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey.

ANSWER: Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit that Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for purposes of this action only.

14. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Denied, except to admit that Xiromed, LLC and Xiromed Pharma España, S.L. collaborate with respect to regulatory approval.

15. On information and belief, Xiromed, LLC is the United States agent acting at the direction of, and for the benefit of, Xiromed Pharma España, S.L. regarding the ANDA.

ANSWER: Admitted for purposes of this action only.

16. On information and belief, Xiromed, LLC is a generic pharmaceutical company that, in coordination with Xiromed Pharma España, S.L. and at the direction of Xiromed Pharma España, S.L., is in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this judicial district.

ANSWER: Denied, except to admit certain corporate Xiromed entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States.

17. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. operate as a single integrated business.

ANSWER: Denied.

18. On information and belief, Xiromed, LLC has a regular and established, physical place of business in New Jersey.

ANSWER: Admitted.

19. On information and belief, Xiromed, LLC intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Product.

ANSWER: Denied, except to admit that Xiromed, LLC intends to benefit if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Product.

20. On information and belief, Xiromed Pharma España, S.L., intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Product.

ANSWER: Denied, except to admit that Xiromed Pharma España, S.L intends to benefit if the ANDA is approved.

21. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. actively participated in the submission of the ANDA to the FDA.

ANSWER: Denied.

22. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. work in privity and/or concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States, including in this judicial district, prior to the expiration of the Asserted Patent.

ANSWER: Denied, except to admit that Xiromed, LLC and Xiromed Pharma España, S.L. collaborate with respect to regulatory approval.

23. In the alternative, this Court has personal jurisdiction over Xiromed Pharma España, S.L. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Xiromed Pharma España, S.L. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Xiromed Pharma España, S.L. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Xiromed Pharma España, S.L. satisfies due process.

ANSWER: Paragraph 23 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for purposes of this action only.

24. Xiromed, LLC has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation and principal place of business for Xiromed, LLC.

ANSWER: Admitted.

25. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed does not contest venue in this Court for purposes of this action only.

26. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Xiromed, LLC is organized under the laws of the State of New Jersey and therefore "resides" in this judicial district, and has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Xiromed Pharma España, S.L is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed does not contest venue in this Court for purposes of this action only.

27. On information and belief, Xiromed, LLC has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps

indicating its intent to market the ANDA Product in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed, LLC does not contest venue in this Court for purposes of this action only.

28. On information and belief, Xiromed, LLC has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Xiromed, LLC maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent a response is required, denied, except to admit Xiromed, LLC has a place of business in New Jersey and does not contest venue in this Court for purposes of this action only.

29. On information and belief, Xiromed Pharma España, S.L and Xiromed, LLC have taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate their intent to market the ANDA Product. As set forth above, on information and belief, if the ANDA is approved, Xiromed intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

ANSWER: Denied, except to admit Xiromed prepared the ANDA, communicated with the FDA, and intends to market the ANDA Product after final FDA approval.

BACKGROUND

30. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was approved by the FDA on April 30, 2019, and which ARI manufactures and sells in this judicial district and throughout the United States.

ANSWER: Denied, except to admit that ARI holds NDA No. 209379 for Selenious Acid and that the 600 mcg Selenium/10 mL version was approved on April 30, 2019.

31. The use of ARI's Selenious Acid products is covered by one or more claims of the Asserted Patent.

ANSWER: Paragraph 31 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 31 of the Complaint, and therefore, Xiromed denies the allegations in Paragraph 31.

32. ARI is the owner of the '957 patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit A.

ANSWER: Denied, except to admit a copy of the '957 patent was attached as Exhibit A to the Complaint.

33. The '957 patent has been listed in connection with ARI's Selenious Acid products in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

ANSWER: Admitted.

34. As indicated in the Orange Book, the patent expiration date for the ’957 patent is July 1, 2041.

ANSWER: Admitted.

35. On information and belief, Xiromed was responsible for preparing the ANDA which contained a Paragraph IV Certification.

ANSWER: Admitted.

36. By letter dated June 11, 2024 (“the First Notice Letter”), Xiromed notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Xiromed had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product prior to the expiration U.S. Patent No. 11,998,565 (“the ’565 patent”), which is at issue in the Related Action.

ANSWER: Admitted.

37. On information and belief, Xiromed submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the ’565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product, or alternatively, that the ’565 patent is invalid.

ANSWER: Denied, except to admit that Xiromed submitted the ANDA to FDA with a Paragraph IV Certification asserting that the ’565 patent is “invalid, unenforceable and/or will not be infringed” by Xiromed.

38. Since ARI received the First Notice Letter and filed its complaint against Xiromed in the Related Action, the ’957 patent has been listed in connection with ARI’s Selenious Acid products in the Orange Book.

ANSWER: Admitted.

39. By letter dated December 6, 2024 ("the Second Notice Letter"), Xiromed notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Xiromed had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product prior to the expiration the '957 patent.

ANSWER: Admitted.

40. On information and belief, the ANDA Product is a generic version of ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Denied, except to admit that the ANDA Product lists ARI's Selenious Acid 600mcg Selenium/10ml (eq. 60mcg Selenium/ml) as the reference listed drug and satisfies the requirements for an ANDA product, including under 21 U.S.C. § 355(j).

41. In the First Notice Letter and the Second Notice Letter, Xiromed disclosed that the ANDA Product is Selenious Acid 600 mcg Selenium/10 mL in an intravenous solution.

ANSWER: Admitted.

42. On information and belief, the ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)).

ANSWER: Denied, except to admit that the ANDA Product includes 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)) and satisfies the requirements for an ANDA product, including under 21 U.S.C. § 355(j).

43. On information and belief, the ANDA Product will feature the same or equivalent

chemical and therapeutic properties as ARI's Selenious Acid products.

ANSWER: Denied, except to admit that the ANDA Product meets the requirements for an ANDA product, including under 21 U.S.C. § 355(j).

COUNT I: INFRINGEMENT OF THE '957 PATENT

44. ARI realleges paragraphs 1–42 as if fully set forth herein.

ANSWER: Xiromed incorporates by reference each of its answers to Paragraphs 1 through 43 of the Complaint as though fully set forth herein.

45. Xiromed submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

46. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Xiromed or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Xiromed's specific intent and encouragement, and will constitute conduct that Xiromed knows or should know will occur. On information and belief, Xiromed will actively induce, encourage, aid, and

abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

ANSWER: Denied and further denied this case is currently subject to 35 U.S.C. § 271(a).

47. On information and belief, Xiromed's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

ANSWER: Denied and further denied this case is currently subject to 35 U.S.C. §§ 271(b) and (c).

48. ARI will be irreparably harmed if Xiromed is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

49. Xiromed has had knowledge of the '957 patent since at least October 11, 2024, when ARI emailed all defendants in the Related Action to inform them that the '957 patent would issue in due course.

ANSWER: Admitted, but not relevant to this case because it the case is not subject to 35 U.S.C. §§ 271(a)-(c).

50. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF

Xiromed denies Plaintiff is entitled to the relief sought against Xiromed in Paragraphs (a)-(h) of the Prayer for Relief or any relief at all for the allegations relating to Xiromed made in the Complaint.

ANSWER TO PLAINTIFF'S JURY DEMAND

Xiromed denies this case is triable by a jury under 35 U.S.C. 271(e).

SEPARATE DEFENSES

On information and belief, Xiromed asserts the following separate defenses to Plaintiff's Complaint.

FIRST SEPARATE DEFENSE

Plaintiff fails to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

The submission of ANDA No. 219476 and/or the manufacture, use, sale, offer for sale and/or importation into the United States of the product covered by ANDA No. 219476 does not and will not directly infringe, indirectly infringe, induce infringement of, or

contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '957 patent. Plaintiff is barred from asserting infringement by the doctrine of prosecution history estoppel and judicial estoppel.

THIRD SEPARATE DEFENSE

Based on information and belief, the claims of the '957 patent are invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

FOURTH SEPARATE DEFENSE

Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

FIFTH SEPARATE DEFENSE

Any defense asserted in any other action in which the '957 patent is asserted that may be asserted in this action.

SIXTH SEPARATE DEFENSE

Plaintiff has waived any alleged defect in the way in which Xiromed's Notice Letter was served.

SEVENTH SEPARATE DEFENSE

Plaintiff's damages, if any, are limited, including under 35 U.S.C. § 287.

DEFENDANTS' COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants and Counterclaim Plaintiffs Xiromed, LLC and Xiromed Pharma España, S.L. ("Xiromed") (collectively, "Defendants" or "Counterclaim Plaintiffs") assert the following counterclaims against Plaintiff and Counterclaim Defendant American Regent, Inc. ("ARI")

(collectively "Plaintiff" or "Counterclaim Defendant").

NATURE OF THE ACTION

1. These counterclaims include claims for a declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 12,150,957 ("the '957 patent).

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

3. Xiromed, LLC is a corporation organized and existing under the laws of the United States with its principal place of business at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

4. Xiromed Pharma España, S.L. is a corporation organized and existing under the laws of Spain with its principal place of business at Manuel Pombo Angulo, 28 3rd Floor, Madrid, Spain, 28050.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Counterclaim Defendant has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this Judicial District.

8. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400, and as a result of Counterclaim Defendant's choice of forum.

FIRST COUNTERCLAIM

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’957 PATENT

9. Counterclaim Plaintiffs reallege and incorporate by reference paragraphs 1 through 8 of these counterclaims as if fully set forth herein.

10. Counterclaim Defendant has alleged in this action that Counterclaim Plaintiffs have infringed the ’957 patent by filing ANDA No. 219476 seeking to obtain approval for the manufacture, use, offer for sale, sale, and/or importation of the 600 mcg/10 mL dosage strength of ARI’s Selenious Acid product, as described by Counterclaim Plaintiffs in ANDA No. 219476 (“the ANDA Product”) and that Counterclaim Plaintiffs’ manufacture, use, offer for sale, sale in the United States, and/or importation into the United States, of the ANDA Product would infringe that patent.

11. Counterclaim Plaintiffs deny that the filing of ANDA No. 219476 was an act of infringement under 35 U.S.C. § 271 and deny that their manufacture, use, offer for sale, sale, and/or importation of the ANDA Product constitutes infringement of the ’957 patent.

12. Counterclaim Defendant’s suit has improperly restrained the free exploitation of Counterclaim Plaintiffs’ ANDA Product by excluding Counterclaim Plaintiffs from entering the market for the proposed drug product described in the ANDA.

13. Counterclaim Plaintiffs have not, do not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the ’957 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the ’957 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

14. A present, genuine, and justiciable controversy exists between Counterclaim Plaintiff, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, and/or importation of a generic version of the ANDA Product infringes any valid and enforceable claim of the ’957 patent.

15. Counterclaim Plaintiffs are entitled to a declaration by this Court that one or more claims of the ’957 patent are not infringed.

16. Counterclaim Plaintiffs are entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

SECOND COUNTERCLAIM

DECLARATORY JUDGMENT OF INVALIDITY OF THE ‘957 PATENT

17. Counterclaim Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs 1–15 of its Counterclaims.

18. Counterclaim Defendant has accused Counterclaim Plaintiffs of infringing claims of the ’957 patent in connection with ANDA No. 219476.

19. Counterclaim Plaintiffs deny infringement of any claim of the ’957 patent because all claims of the ’957 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Counterclaim Plaintiffs cannot infringe the claims of the ’957 patent, including for at least the reasons set forth in the detailed statements included with Counterclaim Plaintiffs’ Notice Letter.

20. The alleged inventions of the ’957 patent lack written description support and do no more than combine familiar elements through known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’957 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art

would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '957 patent and would have had a reasonable expectation of success in doing so.

21. The claims of the '957 patent are invalid at least under 35 U.S.C. §§ 102, 103, and/or 112.

22. Unless Counterclaim Defendant is enjoined, Counterclaim Plaintiffs believe that Counterclaim Defendant will continue to assert that Counterclaim Plaintiffs infringe the claims of the '957 patent and will continue to interfere with Counterclaim Plaintiffs' business.

23. Counterclaim Plaintiffs will be irreparably harmed if Counterclaim Defendant is not enjoined from continuing to assert the claims of the '957 patent and from interfering with Counterclaim Plaintiffs' business.

24. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim Plaintiffs and Counterclaim Defendant concerning the invalidity of the claims of the '957 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

25. Counterclaim Plaintiffs are entitled to a declaratory judgment that the asserted claims of the '957 patent are invalid.

EXCEPTIONAL CASE

26. This case is an exceptional one and Counterclaim Plaintiffs are entitled to an award of their reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiff prays that the Court enter judgment ordering as follows:

(a) adjudicating and declaring that the '957 patent is not infringed and invalid;

(b) if the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Counterclaim Plaintiffs attorneys' fees and costs reasonably incurred in this action; and

(c) granting Counterclaim Plaintiffs such other and further relief as the Court deems just and appropriate.

Dated: January 21, 2025
New York, New York

Respectfully submitted,

/s/ John C. Leddy

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CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2025 I caused a true copy of the above document to be served via email on counsel of record for Defendant via ECF:

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